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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,835	11/19/2001	Gideon Strassmann	MTN-031CN	9376
959	7590	05/17/2004	EXAMINER	
LAHIVE & COCKFIELD, LLP.			WINKLER, ULRIKE	
28 STATE STREET				
BOSTON, MA 02109			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/988,835	Applicant(s) STRASSMANN ET AL.	
	Examiner Ulrike Winkler	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-8 and 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-8 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The Amendment filed February 9, 2004 in response to the Office Action of September 8, 2003 is acknowledged and has been entered. Claims 4, 9 and 10 have been cancelled. Claims 1-3, 5-8, and 11 are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Oath/Declaration

The office acknowledges the copy of the receipt of the petition filed under 37 CFR 1.47(a).

Claim Rejections - 35 USC § 112

The rejection of claims 1-3, 5-8 and 11 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention **is maintained** for reason of record.

Applicant's argument is that a prophetic description of what is envisioned as a GDF-8 inhibitor is sufficient to show one of ordinary skill in the art that Applicant was in possession of the claimed invention. The instant invention is drawn to a "method of increasing expression GLUT4 in a subject" the increase of GLUT4 is accomplished by the administration of undefined GDF-8 inhibitor.

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The claimed invention is drawn to methods of increasing the expression of GLUT4 or a method of increasing insulin sensitivity in a subject by administering a GDF-8 inhibitor. However, no structural or specific functional characteristics of such an peptide fragment inhibitors, GDF-8 receptor agonist, dominant negative mutant GDF-8, a non-GDF-8 peptide, antisense, ribozyme inhibitors and an inhibitor that is derived from the Pro-GDF-8 domain is provided. Although the specification provides a way testing the degree to which a GDF-8 inhibitor blocks the activity of GDF-8 as measured by the ability of GDF-8 to interfere with the differentiation process of 3T3-L1 pre-adipocyte to adipocytes, a method of testing does not provide any insight of the structure of the inhibitor. This situation is analogous to "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it; what is required is a description of the DNA itself"(1401) "an applicants complies with the written description requirement 'by describing the invention with all its claimed limitations, not that which makes it obvious'" (1405) *Regents of the University of California v Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398, (Fed. Cir. 1997). Because one skilled in the art would conclude that the inventors were not in possession of the claimed invention. The claim fails to comply with the written description requirement.

The rejection of claims 1-3, 5-8 and 11 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is **maintained** for reason of record.

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Applicant's arguments have been fully considered but fail to persuade. Applicant's argument is that the specification provides a method of screening for inhibitors.

A method of testing the degree to which a GDF-8 inhibitor blocks the activity of GDF-8 as measured by the ability of GDF-8 to interfere with the differentiation process of 3T3-L1 pre-adipocyte to adipocytes, does not provide any insight in how to make and use the inhibitor in a subject. The specification does not set forth sufficient teachings to allow one skilled in the art to use any compound besides an anti-GDF-8 antibody. Using inhibitors such as dominant negative mutant of GDF-8, a GDF-8 receptor agonist, a non-GDF-8 peptide, an antisense nucleic acid or ribozyme is unpredictable in the dynamic physiological setting of a subject. The specification provides insufficient guidance with regard to these issues and provides no working examples which would provide guidance to one skilled in the art and no evidence has been provided which would allow one of skill in the art to predict the efficacy of the claimed method of treatment and composition with a reasonable expectation of success in regards to using a dominant negative mutant of GDF-8, a GDF-8 receptor agonist, a non-GDF-8 peptide, an antisense nucleic acid or ribozyme. Moreover, the nature of the invention and the state of prior art have not provided any reasonable expectation of success especially in regards to antisense nucleic acid or ribozyme inhibitors in the context of a subject. For the above reasons, it appears that undue experimentation would be required to practice the claimed invention with a reasonable expectation of success.

The instant fact pattern fails to disclose any particular structure for the claimed inhibitors. The specification does not provide any guidance or any working examples in this unpredictable art, and thus the artisan would have been unable to prepare the claimed GDF-8 inhibitor without

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undue experimentation. Treatment/administration protocols depend upon the nature of the compound being administered as well as the clinical condition of the subject or patient. In the absence of additional information the skilled artisan would not have been able to use the undisclosed compound(s) for treatment without undue experimentation.

Double Patenting

The rejection of claims 4, 9, 10 under 35 U.S.C. 101 as claiming the same invention as that of claims 1-7 of prior U.S. Patent No. 6,368,597 **is withdrawn** in view of Applicant's cancellation of the claims.

The rejection of claims 1-3, 5-8 and 11 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-7 of U.S. Patent No. 6,368,597 **is maintained**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are drawn to treatment methods with an antibody inhibitor.

Applicant's have indicated that they will file terminal disclaimer once allowable subject matter has been indicated.

Conclusion

No claims allowed.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

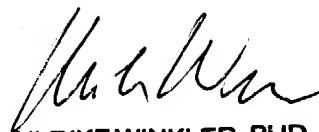
Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989). The Group 1600 Official Fax number is: (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 571-272-0912. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 571-272-0902.


ULRIKE WINKLER, PH.D.
PATENT EXAMINER

5/14/04